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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,953	04/02/2004	Itzhak Bentwich	050992.0201.04USCP	2952
37808	7590	11/28/2007	EXAMINER	
ROSETTA-GENOMICS			PITRAK, JENNIFER S	
c/o PSWS			ART UNIT	
700 W. 47TH STREET			PAPER NUMBER	
SUITE 1000			1635	
KANSAS CITY, MO 64112			MAIL DATE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/708,953	Applicant(s) BENTWICH, ITZHAK	
	Examiner Jennifer Pitrak	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/03/06</u> + <u>4/2/04</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-16, in the reply filed on 10/25/07 is acknowledged. Applicant has cancelled claims 1-17 and has added new claims 18-29, which correspond to the elected Group I. Applicant has further elected SEQ ID NO: 2240728, which comprises SEQ ID NO: 8385 as shown below. Claims 18-29 are currently under examination.

SEQ ID NO: 2240728

5' -TCTCAAGCTGTGACTGCAAAGGGAAGCCCTTTCTGTTGTCTAAAAGAAAAGAAAGTGCTTCCCTTTGGTGAATTACGGTTTGAGA-3'

SEQ ID NO: 8385

|||||
5' -AGAAAGTGCTTCCCTTTGGTGA-3'***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention that is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

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The disclosure of the prior-filed applications, Application Nos. 10/708,204 and 10/707,980, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The instantly claimed SEQ ID NOs: 2240728 and 8385 are not disclosed in the prior-filed applications. Thus, the instant claims have the benefit of the instant filing date, 04/02/04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18 and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hood, *et al.* (US PG PUB 2002/0150891).

The claims are drawn to an isolated nucleic acid consisting of 16-120 nucleotides wherein the sequence of the nucleic acid comprises a sequence complementary to a sequence at least 80% identical to 16 or more consecutive nucleotides of SEQ ID NO: 2240728 (claim 18) and to a vector comprising the nucleic acid (claim 24).

Hood *et al.* teach the isolated nucleic acid consisting of SEQ ID NO: 470 and recombinant expression vectors comprising SEQ ID NO: 470 (p.3, paragraph [0019]). SEQ ID NO: 470 of Hood, *et al.* is 16 nucleotides in length and has complementarity to 13 nucleotides of the instantly claimed SEQ ID NO: 2240728 from nucleotide positions 42-54 as shown.

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SEQ ID NO: 2240728 (nt 36-59)

5' -UUGUCUAAAAGAAAAGAAAGUGCU-3'

SEQ ID NO: 470

3' -TCTTTTCTTTTCTTTT-5'

Thus, Hood, *et al.* clearly anticipate the instant claims 18 and 24.

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to isolated nucleic acid molecules 16-120 nucleotides in length with at least 80% identity to SEQ ID NO: 2240728. According to the instant specification, the claimed molecules are “genomic address messenger” or “GAM” genes, which are related to miRNAs (p.17, paragraphs [0022] and [0023]). Also, according to the specification, the GAMs specifically inhibit translation of one or more target genes by hybridization to an untranslated region (UTR) of a target mRNA (p.20, paragraph [0032]. The specification generally states that

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the GAMs may be useful for downregulating expression of genes including disease-associated genes.

The specification provides no evidence that any of the predicted nucleic acid molecules, including SEQ ID NO: 2240728, actually function as a miRNA-like molecule or otherwise. The specification provides no evidence that the nucleic acid molecules exist endogenously. As was known at the time of filing, prediction of miRNAs yielded predictions that were not valid, i.e., many predicted miRNAs had no biological function. For example, John, *et al.* (2004, PLoS Biology, v.2, 1862-1879) reported prediction of miRNA targets using an algorithm based on several factors including sequence complementarity between miRNA and target site and evolutionary conservation of the target sequence (see p.1864, second paragraph). The authors commit most of pages 1864-6 and Table S8 of their summary article to explaining their methods of validating predicted miRNA targets, specifically noting that “only a small number of target sites of target genes regulated by miRNAs have been experimentally verified,” (p.1864, last paragraph). At p.1865 in the sixth paragraph, the authors report that “The percentage of false positives for target transcripts with more than two, three, and four sites is 39%, 30%, and 24%, respectively,” and that the false-positive rate for single sites is about 35%. Furthermore, the authors indicate that the usefulness of their prediction method is to facilitate focused experiments (abstract) and to facilitate evaluation of the predictions (p.1864, fifth paragraph). Thus, although miRNA target predictions were accomplished, the real-life value of each predicted miRNA needed to be assessed by experimentation. Therefore, the instantly claimed nucleic acid molecules have no known value or utility except as one of millions of possibly useful molecules and therefore lack credible utility.

Claims 18-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

Claims 18-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to nucleic acid molecules as described above, including those with as little as 80% identity to a portion of SEQ ID NO: 2260728, that have not been adequately described in the specification to demonstrate that they actually function like miRNAs. Although the isolated nucleic acid molecules comprising 100% identity to a portion of SEQ ID NO: 2240728 can be clearly envisioned and could be synthesized, their proposed endogenous existence, function, and target mRNAs have not been described in the instant specification. This further renders all of the possible nucleic acid molecules with 80-99% sequence identity to SEQ ID NO: 2240728 undescribed to convey possession of the claimed molecules. If the perfectly complementary molecules had the proposed function, it is not clear which of the possible 80-99% complementary molecules would have the proposed function. Thus, claims 18-29 are not

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adequately described to demonstrate possession of the claimed nucleic acid molecules.

Claims 18-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to the nucleic acid molecules as described above. The function of the claimed molecules is not known nor demonstrated per the instant specification. Although the instantly claimed molecules are described to function like miRNAs, there is no support for such a function in the specification nor in the prior art. Furthermore, as previously described above under the 35 USC §101/112 rejection, the utility of the endogenous molecules of the instant application is not known and there is significant error in prediction of miRNA-like molecules and their targets. Thus, the claims are not enabled.

Closing

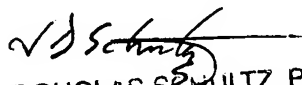
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Pitrak whose telephone number is 571-270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak
Patent Examiner
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SUPERVISORY PATENT EXAMINER